

REMARKS

Claims 1-29 are currently pending. The Examiner has rejected claims 1-5, 7-14, 16-23, and 25-29. Claims 6, 15, and 24 are objected to.

Claim Rejections

35 U.S.C. 112, second paragraph

The Office Action rejected claims 1-18 “under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant[s] regard as the invention.” Specifically, the Examiner stated that “it is not clear as to what ‘armpit areas’ encompasses. It is not clear if it is just an area of the garment or of the wearer or if it includes fabric therein.” The Examiner further states that “Applicant[s] specification only states ‘armpit patterns’ and not armpit areas.”

As an initial matter, Applicants respectfully submit that literal support for the claim element “armpit areas” is found at page 8, line 10 and at page 15, line 6 of Applicants’ specification, and in claim 7, as originally presented. The Examiner’s assertion is simply false; literal support for the claim element is found in the specification.

As to what is and is not included by the claim element “armpit areas”, there can be no doubt. Elements 34 of FIGS. 1 and 5 clearly show the armpit areas, and the entire specification makes clear that the armpit areas include fabric, are part of the breast self-examination apparatus, and refer not only to the wearer’s armpit *regions* (note the appropriate use of dissimilar terminology throughout the specification for these different structures). Thus, there is no rational basis for the Examiner’s conclusion regarding the clarity of the claim element at issue.

Accordingly, Applicants respectfully request withdrawal of the rejection of claims 1-18 under 35 U.S.C. 112, second paragraph.

35 U.S.C. 102

The Office Action rejected claims 1-5, 8, and 28 under 35 U.S.C. 102(b) as being anticipated by United States Patent Number 5,479,661 to Fingleson *et al.* (“Fingleson *et al.*”).

To anticipate a claim, the reference must teach every element of the claim. “A claim is only anticipated if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP 2131.

As to claims 1-5 and 8, Applicants respectfully submit that Fingleson *et al.* fail to teach “a form-fitting garment comprising armpit areas”, as claimed. Specifically, Fingleson *et al.* fail to teach a “form-fitting” garment¹. The device of Fingleson *et al.* allows insertion of a hand between the user’s body and the device, and is thus not “form-fitting”. Furthermore, Fingleson *et al.* fail to teach “armpit areas”². Instead, Fingleson *et al.* merely teach a fabric, paper, or plastic bib (see col. 3, lines 2-3 and Figs. 1, 2, 4, 6, and 8), having “open sides” (see e.g. col. 4, line 19) through which a user may insert a hand to perform an examination underneath the bib (see e.g. FIG. 8 and col. 2, lines 24-27 and col. 4, lines 19-21). As such, Fingleson *et al.* fail to teach a shirt, and fail to teach anything regarding the thickness of the material from which the garment is formed or the lubricity of such material. This is not unexpected, however, since

1 The claim element “form-fitting” is 1) defined in the written description at page 7, lines 18-23, at page 9, lines 16-19, and at page 13, lines 13-21 as conforming to the body; 2) shown in FIG. 5 as conforming to the body; and 3) defined by Merriam-Webster as “conforming to the outline of the body: fitting snugly” (See attached Exhibit A). Applicants expressly request that the Examiner make Exhibit A a part of the record.

2 The Examiner admits that Fingleson *et al.* fail to teach a garment comprising armpit areas. See page 4, line 3.

Fingleson *et al.* do not contemplate an examination of breast, or any other, tissue from an outside of the garment. To conclude otherwise is clearly erroneous.

Nonetheless, the Examiner stated, at page 3, lines 6-10, that “[t]he Fingleson apparatus comprises a low coefficient of friction since it allows the movement of the hands on the surface of the garment about the breasts with the examination pattern disposed on the garment so that it overlies a breast of the wearer as claimed in claims 3 and 4. (See Fingleson col. 3, line 35- col. 4, line 23).” A careful reading of the cited section, however, reveals that, in fact, Fingleson *et al.* is completely devoid of any reference to the level of friction of the material for the garment. Instead, Fingleson *et al.* state that the garment may be formed of paper or plastic, which materials are not only not form-fitting, but do not have a low coefficient of friction to facilitate hand and finger movement over an examination pattern.

As to claim 28, Applicants respectfully submit that Fingleson *et al.* further fail to teach the step of examining the breast from the outside of the garment, as required by the claim. Specifically, and directly to the contrary, Fingleson *et al.* teach examining the breast from inside the garment (*see* col. 4, lines 11-20 and FIG. 8).

Thus, since Fingleson *et al.* fail to teach each and every limitation of at least claims 1, 2, 3, and 28, Applicants respectfully request that the Examiner withdraw the rejection of claims 1-5, 8, and 28 under 35 U.S.C. 102(b).

35 U.S.C. §103

As a preliminary matter, “the examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness.” MPEP 2142. “To establish a *prima facie* case of obviousness. . . the prior art reference (or references when combined) must teach or suggest all

the claim limitations.” MPEP 2142. “[I]mpermissible hindsight must be avoided and the legal conclusion [of obviousness] must be reached on the basis of the facts gleaned from the prior art.” MPEP 2142.

Fingleson *et al.* and Morrison

The Office Action rejected claims 7, 11-14, and 16 under 35 U.S.C. 103(a) as being unpatentable over United States Patent No. 5,479,661 to Fingleson *et al.* in view of United States Patent Number 4,873,982 to Morrison (“Morrison”).

As to claim 7, Applicants respectfully submit that Morrison does not remedy the deficiencies of Fingleson *et al.* with regard to the teaching of armpit areas. Specifically, Morrison does not teach a garment with armpit areas, but merely teaches a “tube top”, which does not extend over the armpit region of the wearer. *See* Figs. 1 and 3, and col. 3, line 62. Nonetheless, the Examiner stated, at page 3, that Morrison teaches, “that the garment is adapted for use in other areas of the body where the detection of lumps is desired (such as the underarm area). (See Morrison, col. 4, lines 18-27).” The cited section of Morrison, however, does not teach using the garment for examination of the lymph nodes in the armpit area, but merely indicates that, broadly speaking, the inventive multi-ply construction of the device of Morrison may be used with “suitable garments. . . specifically adapted for use with other parts of the body.” The only teaching of an examination pattern disposed on an armpit area of an examination garment comes from Applicants’ own disclosure, and thus, it is clear that the Examiner has used impermissible hindsight in formulating the rejection. Simply put, the vague teaching of Morrison is insufficient to support the Examiner’s conclusion of obviousness, and fails to specifically teach the claimed armpit areas.

As to claims 11-14 and 16, Applicants respectfully submit that Fingleson *et al.* and Morrison, as combined, fail to teach each and every element of the claims, and that the Examiner's conclusion of obviousness relies on impermissible hindsight at least for the reasons stated above as to claim 7. Namely, neither Fingleson *et al.* nor Morrison teaches an armpit examination pattern disposed on a form-fitting garment. Furthermore, neither cited reference teaches a garment having two separate examination patterns for examination of separate areas of the wearer's body.

With regard to claims 12 and 13, Applicants respectfully submit that Fingleson *et al.* and Morrison fail to teach that the garment is a shirt formed from a thin material, or that the garment comprises a low coefficient of friction to facilitate hand and finger movement *over the examination patterns*. As discussed above, Fingleson *et al.* fail to teach these elements, and Morrison fails to remedy such deficiency. Specifically, the device of Morrison is not a shirt, and does not have the claimed armpit areas. Furthermore, while Morrison discusses frictional considerations, Morrison is concerned only with friction between contacting surfaces of adjacent plies, and teaches nothing with regard to a level of friction between the user's hand and fingers over an examination pattern on the outside of the device³. See col. 2, lines 35-44.

Fingleson *et al.* and Rusin

The Office Action rejected claims 9, 10, 19-23, 25-27, and 29 under 35 U.S.C. 103(a) as being unpatentable over Fingleson *et al.* in view of United States Patent Number 6,412,491 to Rusin ("Rusin").

³ This distinction is significant because the device of Morrison works by sliding interaction between the first and second ply, wherein the fingers of a user "stick" to the outside surface of the outer ply. Accordingly, this teaches away from Applicants' outer surface having a low coefficient of friction surface to facilitate hand and finger movement thereover.

As to claims 9, 10, and 29, Applicants respectfully submit that Rusin fails to remedy the deficiencies of Fingleson *et al.*, i.e. the failure to teach armpit areas and the failure to teach examination from outside the garment. Rusin merely teaches a planar film, which is not a form-fitting garment, and does not comprise an armpit area extending over an armpit region of a user. See Fig. 1⁴. Thus, the cited teachings of Rusin are irrelevant inasmuch as the Examiner has failed to establish where the prior art teaches a form-fitting garment comprising armpit areas.

As to claim 19, Fingleson *et al.* and Rusin fail to teach a t-shirt element. Neither the bib of Fingleson *et al.*, nor the planar film of Morrison can reasonably be construed to teach a t-shirt, and neither allows the same function as a t-shirt. Specifically, the bib of Fingleson *et al.* is intended to be used with a hand underneath the garment, and the planar film of Morrison lacks the positioning and secure attachment features provided by the t-shirt of the present invention. Furthermore, neither provides the comfort and ease of use provided by the t-shirt examination device of the present invention.

With regard to claims 20 and 21, Fingleson *et al.* and Rusin further fail to teach the thin material or the low coefficient of friction for facilitating movement of the user's hand and fingers over an examination pattern.

Fingleson *et al.*, Morrison, and Rusin

The Office Action rejected claims 17 and 18 under 35 U.S.C. 103(a) as being unpatentable over Fingleson *et al.* in view of Morrison, and further in view of Rusin.

⁴ While Fig. 2 may appear to show the device covering an armpit region of a user, no specific teaching is made to that effect. Furthermore, the film cannot be construed as including a specific "armpit area" specially designed for use with the user's armpit region. Finally, the film of Rusin is non-elastic, and thus is unsuitable use with the contours of a user's armpit region. See Abstract, for example.

As discussed above, Fingleson *et al.*, Morrison, and Rusin all fail to teach the form-fitting garment having an armpit examination pattern. Thus, at least for that reason, the rejection of claims 17 and 18 is improper.

Accordingly, Applicants respectfully request withdrawal of the rejections of claims 1-5, 7-14, 16-23, and 25-29.

Response to Arguments

Applicants specifically point out and object to any reliance on, or consideration of, the hearsay, allegations, and/or conclusions of others contained at page 8, lines 1-2, of the Office Action, and not made a part of the record. Applicants further point out and object to any reliance on, or consideration of, any evidence of devices constituting prior art that has not been made a part of the record (*See* page 6, lines 16-17) including the definition of the phrase “shirt” provided (*See* page 6, lines 17-19).

CONCLUSION

Applicants respectfully submit that pending claims 1-29 are in condition for allowance, at least for the reasons stated above, and respectfully request that the Examiner withdraw the rejection of claims 1-5, 7-14, 16-23, and 25-29.

If the Examiner has any questions or concerns, Applicants request that the Examiner contact Applicants' undersigned attorney.

Respectfully submitted,

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